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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,372	06/04/2001	Roland Henri	JAB-1430	3181

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EXAMINER	
SHAHNAN SHAH, KHATOL S	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/857,372	HENRI ET AL.	
	Examiner	Art Unit	
	Khatol S Shahnan-Shah	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *4,6,10,11 and 20-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,7-9,12-19,29 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-30* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 June 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response dated 3/15/2004 to the restriction requirement mailed 2/24/2004 is acknowledged. Applicants elected Group I, claims 1-9, 12-19, 29 and 30 with traverse. The traversal was on the ground that applicants note that the application as filed contains 30 claims. The examiner wants to clarify this matter. It appears that the electronic version of the application had contained two different set of claims. The original set of claims which constituted 34 claims starting at page 37 of PCT application number PCT/EP99/09833 were listed as claims for the current application. Those set of the claims were the set, which was considered by the examiner on the restriction requirement mailed 2/24/2004. After receiving applicants' response the examiner discovered a 85 page amendment dated 6/4/2001 scanned as a miscellanous incoming letter into the electronic system. This amendment contained a new specification, abstract, figures, sequence listing a new set of claims containing 30 claims starting on page 65 of the submitted material. The Examiner discussed the above issues on a telephonic interview with applicants attorney Ms. Laura A. Donnelly (reg # 38435) on 6/14/2004. Based on the new set of claims a new restriction and election will follow:

Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-9, 12-19, 29 and 30 are drawn to nucleic acids and host cells.

Group II, claim(s) 10-11, 20 and 22 are drawn to polypeptides.

Group III, claim(s) claims 22-24 are drawn to a method of identifying compounds and a compound produced by such method.

Group IV, claim(s) 25-27 are drawn to a method of identifying DNA sequences.

Group V, claim(s) 28 is drawn to an antibody.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature linking group I-V appears to be a nucleic acid molecule comprising the genomic DNA of *Candida albicans.* However, genes of *Candida albicans* have been isolated and known in the art. (see abstract in Gene, vol. 187, No. 2, pp. 151-158, 1997)

Therefore, the technical feature linking the inventions of groups I- V does not constitute a special technical feature as defined by the PCT Rule 13.2, as it does not define a contribution over the prior art. As set forth above, each of group I-V has a special technical feature that is not required for the other groups.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Election

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

a) If applicants elect group I, then there are additional election of species.

Please choose one of the nucleic acid sequences from SEQ ID 1-9.

Please choose one of the nucleic acid species from claims 4, 5, 6.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species are shown to be distinct because they are drawn to a plurality of disclosed patentably distinct sequences which are structurally and functionally distinct molecules.

4. During a telephone conversation with Ms. Laura A. Donnelly (reg # 38435) on 6/14/2004 a provisional election was made without traverse to prosecute the invention of group I, claims 1-9, 12-19, 29 and 30. Applicant also elected species of SEQ ID NO: 1 and DNA species from claim 5. Affirmation of this election must be made by applicant in replying to this Office action.

5. Claims 1-30 are pending in this application. Claims 4, 6, 10, 11 and 20-28 are withdrawn from further consideration by the examiner, under 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Claims 1-3, 5, 7-9, 12-19, 29 and 30 are under consideration.

Information Disclosure Statement

7. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A (1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

8. The disclosure is objected to because of the following informalities:

9. This application contains sequences in the specification, which do not comply with 37 CFR 1.821 (d) for failing to reference to the sequences by use of sequence identifiers, preceded by " SEQ ID NO". For example see page 22.

10. The use of the trademarks Invitrogen, Qiagen, PathoSeq etc. have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Appropriate corrections are required.

Drawings

11. This application lacks formal drawings. The informal drawings filed in this application are acceptable for examination purposes. When the application is allowed, applicant will be required to submit new formal drawings.

Priority

12. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Claim Rejections - 35 USC § 101

13. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

14. Claims 1-3, 5, 7-9 and 18 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-3, 5, 7-8 and 18 are drawn to a nucleic acid molecule which does not indicate the hand of man and is considered a product of nature.

Claim 9 is drawn to cell containing a nucleic acid molecule which does not indicate the hand of man and distinguish the claimed cell from a product of nature.

Claim Rejections - 35 USC § 101and 35 U.S.C. 112

15. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. The pending claims have been reviewed in light of the utility examination guidelines.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" – A utility that is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention.

"Substantial"- A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a " real world" context of use are not substantial utilities.

"Credible"- Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

" Well-established"- A specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. (see MPEP 2107-2107.02).

17. Claims 1-3, 5, 7-9, 12-18, 29 and 30 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to it not being supported by a specific, substantial, and credible utility or a well- established utility.

The claims are drawn to polynucleotides. The claimed polynucleotides are not supported by a specific asserted utility because the disclosed uses of the polynucleotides are not specific and are generally applicable to any polynucleotides. For example, the specification states that the polynucleotides can be used in composition of matter comprising an antisense nucleic acid molecule (see page 4). All these possible uses are generic to any polynucleotides. As a matter of fact, the specification summarizes pretty much of the modern biotechnology in general, but fails to connect the specifically elected polynucleotide(s) to any particular or specific utility.

Further, the claimed polynucleotides are not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, the specification states that the polynucleotides may, advantageously, be included in a suitable expression vector to express polypeptides encoded therefrom in a suitable host (see page 9, line 27-30). However, this is not a real world utility because all these possible uses are generic to any polynucleotides .The polynucleotides are used in research to find other things that might possess real world utility. The apparent need for such research clearly indicates that the polynucleotides are not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial utility in those instances where the final product is not supported by a specific and substantial utility. Identifying and studying the properties of a protein encoded by a polynucleotide itself or the mechanisms in which the protein is involved does not define a "real world" context for use. Similarly, the other possible

listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds.

Please note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed.

The specification as filed does not disclose or suggest any property or activity for the claimed polynucleotides such that another non-asserted utility would be well established for the claimed invention.

18. Claims 1-3, 5, 7-9, 12-18, 29 and 30 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention lacks patentable utility due to it not being supported by a specific, substantial, and credible utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

19. Claims1-3, 5, 7-9, 12-19, 29 and 30 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid molecule encoding a polypeptide, does not reasonably provide enablement for fragments or derivatives of said nucleic acid or a method for treating a *Candida albicans* disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP) 2164.01(a). Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure

would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples (6) the quantity of experimentation, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The instant claims are drawn to nucleic acid molecules encoding a polypeptide consisting nucleic acid sequences of SEQ ID NO: 1 to SEQ ID NO: 9. Claims 3, 29 and 30 recite fragments or derivative from these variant sequences. These terms can read on as few as one or more nucleotides.

The breadth of the instant claims is drawn to fragments or derivative, which are not specified in the sequence disclosure. However the specification provide no guidance as to what nucleotides may be changed without causing a detrimental effect to the nucleic acid molecule and to the protein which being encoded by this particular nucleic acid. Further, it is unpredictable as to which nucleotide could be removed and which could be added. It is also unclear how these sequences are selected or how the skilled artisan would predict the sequences required accomplishing the required function. The specification does not teach how one would make this selection or teach a method to predetermine the sequence structure for appropriate selection to result in the required changes. Claim 19 recites a method for treating a *Candida albicans* associated disease comprising administering a composition comprising an antisense nucleic acid molecule. The specification does not teach how this composition is administered. The specification presents a paper protocol in this regard. In contrast to direct protein used in treating disease nucleic acids are required to target appropriate cell types within a host, become transcriptionally

active, appropriately process any encoded proteins and present such proteins to the host in a manner suitable for recognition by the host's immune system. Such a "gene therapy" approach to

epitope delivery suffers from all the limitations associated with gene therapy technology. However, as of 12/95, the artisan did not accept, in the absence of suitable and particular guidance, that such could have been accomplished without having had to have exercised undue experimentation. See e.g. NIH Report Reference. Applicants' specification fails to provide guidance to the skilled artisan on the parameters for DNA therapy for the breadth of the claimed invention. Numerous factors complicate the gene therapy art, which have not been shown to be overcome by routine experimentation. These include, the fate of the DNA vector itself (volume of distribution, rate of clearance into the tissues, etc.), the *in vivo* consequences of altered gene expression and protein function, the fraction of vector taken up by the target cell population, the trafficking of the genetic material within cellular organelles, the rate of degradation of the DNA, the level of mRNA produced, the stability of the mRNA produced, the amount and stability of the protein produced, and the protein's compartmentalization within the cell, or its secretory fate, once produced. These factors differ dramatically based on the vector used, the protein being produced, and the disease being treated.

Additionally, the specification does not provide any working examples which enable the claimed invention.

In view of all of the above, in view of the lack of predictability in the art, and lack of guidance on how to obtain the desired fragments and derivatives it is determined that it would require undue experimentation to make and/or use the claimed invention. In summary, the actual invention is not described in such a way that one skilled in the art could

grasp the invention and make and/or use the invention and/or reproducibly practice the invention with a reasonable expectation of success, without undue experimentation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with the claims since the specification gives no guidance on or exemplification of how to anticipate the specific fragments or derivatives thereof.

20. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

21. Claims 3, 7, 8, 13, 19, 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites " nucleic acid selected from SEQ ID NO: 1 or SEQ ID NO: 2 and fragments or derivatives of" which renders the claim indefinite by reciting improper Markush language. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as Markush group, recites members as being " selected from group consisting of A, B and C". See Ex parte Markush, 1925 C.d. 126 (Comm'r Pat 1925).

Claims 3, 29 and 30 are vague and indefinite due to the phrase " or fragments or derivatives". A fragment reads on as few as one nucleotide.

It is not clear what constitutes the metes and bounds of " a molecule complementary to the first nucleic acid" recited in claim 13.

Claims 7, 8 and 13 recite the phrase "a nucleic acid capable of hybridizing to a second nucleic acid ". It is unclear what constitutes the metes and bounds of said phrase.

Claim 19 recite the phrase "a nucleic acid capable of binding to ". It is unclear what constitutes the metes and bounds of said phrase.

Conclusion

22. No claims are allowed.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (571)-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645
June 24, 2004

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER